

REMARKS

Claims 1 and 8-12 are pending. Claims 2-4 and 5-8 were previously cancelled without prejudice to or disclaimer of the underlying subject matter. No amendments have been presented. No new matter enters by way of this response.

I. Rejection under 35 U.S.C. §101

Claims 1 and 6-12 stand rejected under 35 U.S.C. § 101, because the claimed invention allegedly lacks patentable utility. Final Action at page 2. Applicants respectfully traverse this rejection.

The specification provides a specific, substantial, and credible utility for SEQ ID NO: 7212 and complements thereof. For example, the specification clearly discloses that SEQ ID NO: 7212, a sequence of approximately 69,000 bases, contains sequences that encode for numerous proteins, including 30S Ribosomal protein S30, gibberellin C-20 oxidase, and several receptor protein kinase-like proteins, and provides the positions of the encoding sequences of these proteins. *See, e.g.*, specification at page 37, line 5 through page 42, line 6, Table 1, and the sequence listing. The skilled artisan would understand the role of such proteins. In addition, the specification also discloses that the nucleic acid molecules can be used to monitor the expression of such proteins, for example in a cell. *See, e.g.*, specification at page 68, lines 3-23, and Table 1. One of ordinary skill in the art would recognize that the claimed nucleic acid molecules have utility, for example, to identify markers and isolate promoters associated with the proteins disclosed as encoded in the approximately 69,000 base pair SEQ ID NO: 7212, including 30S Ribosomal proteins, gibberellin C-20 oxidase, and receptor protein kinase-like

proteins upon reading the present specification. These utilities are immediately apparent for the claimed nucleic acid molecules without further research.

The “basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility...where specific benefit exists in currently available form.” *Brenner v. Manson*, 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Applicants have met this part of the bargain – the present specification discloses nucleic acid molecules which, in their current form, provide at least one specific benefit to the public, for example, their use to encode a 30S Ribosomal protein S30, gibberellin C-20 oxidase, and several receptor protein kinase-like proteins. *See, e.g.* Specification at page 37, line 5 through page 42, line 6, and Table 1. This benefit is specific, not vague or unknown, and it is a “real world” or substantial benefit.

The “threshold for utility is not high: An invention is ‘useful’ under section 101 if it is capable of providing some identifiable benefit.” *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) (“when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown”).

The Federal Circuit has recently provided guidance as to the kind of disclosure an application could contain to establish a specific and substantial utility. *In re Fisher*, 421 F.3d 1365, 76 U.S.P.Q.2d 1225 (Fed. Cir, 2005). First, the Court indicated that the specification disclose “that an invention is useful to the public as disclosed in its current

form.” *Id.* at 1371. Second, the Court further noted that the specification “also show that that claimed invention can be used to provide a well-defined and particular benefit.” *Id.* Applicants have provided nucleic acid sequences which are shown in the specification to correlate to known genes. Such a correlation is sufficient to satisfy the utility standard. *Id.*

The present specification discloses specific and substantial uses for the claimed nucleic acid molecules, including that they encode proteins such as 30S Ribosomal protein S30, gibberellin C-20 oxidase, and several receptor protein kinase-like proteins (*see, e.g.*, specification at page 37, line 5 through page 42, line 6, and Table 1 and the sequence listing); use to identify polymorphisms related to such proteins (*see, e.g.*, specification at page 60, line 26 through page 68, line 2); use to transform plants to modify the expression of such genes (*see, e.g.*, specification at page 73, line 7 through page 89, line 11); and to monitor the expression of such proteins or mRNA associated with those proteins (*see, e.g.*, specification at page 68, lines 3-23).

One of ordinary skill in the art would recognize that the claimed nucleic acid molecules have utility, for example, they encode numerous proteins, such as 30S Ribosomal protein S30, gibberellin C-20 oxidase, and several receptor protein kinase-like proteins. These utilities are immediately apparent for the claimed nucleic acid molecules without further research.

An examiner must accept a utility by an applicant unless the Office has evidence or sound scientific reasoning to rebut the assertion. *See In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992). “More specifically, when a patent application claiming a nucleic acid asserts a specific, substantial, and credible utility, and

bases the assertion upon homology to existing nucleic acids or proteins having an accepted utility, the asserted utility must be accepted by the examiner unless the Office has sufficient evidence or sound scientific reasoning to rebut such as assertion.” Federal Register 66(4):1096, Utility Guidelines (2001). “[A] ‘rigorous correlation’ need not be shown in order to establish practical utility; ‘reasonable correlation’ is sufficient.” *See, Fujikawa v. Wattanasin*, 93 F.3d 1559, 1565, 39 U.S.P.Q.2d 1895, 1900 (Fed. Cir. 1996). “An Applicant can establish this reasonable correlation by relying on statistically relevant data documenting the activity of the compound or composition, arguments or reasoning, documentary evidence, or any combination thereof.” M.P.E.P. § 2107.03, at page 2100-43. Applicants have demonstrated such a reasonable correlation.

The claimed nucleic acid molecules are disclosed to encode proteins, such as 30S Ribosomal protein S30, gibberellin C-20 oxidase, and to encode several receptor protein kinase-like proteins. The specification provides ample correlation between the claimed nucleic acid molecules and the recited proteins. Accordingly, the use of the claimed nucleic acid molecules to encode the disclosed protein or fragment thereof satisfies the utility requirement of 35 U.S.C. § 101.

Applicants have disclosed a specific, substantial and credible utility for the claimed nucleic acid molecules. Any one of these utilities is enough to satisfy the requirements of 35 U.S.C. § 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the rejection under Section 101 is incorrect. Reconsideration and withdrawal of this rejection are respectfully requested.

II. Rejection under 35 U.S.C. § 112, first paragraph, Enablement

Claims 1 and 8-12 stand rejected under 35 U.S.C. § 112, first paragraph as not enabled because the claimed invention allegedly lacks utility. Final Action at page 6. Applicants respectfully traverse this rejection for the reasons set forth above regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph is improper. Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

III. Rejection under 35 U.S.C. § 112, first paragraph, Written Description

Claims 1 and 8-12 stand rejected under 35 U.S.C. § 112, first paragraph because the claimed subject matter allegedly was “not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.” Office Action mailed August 12, 2003 at page 11. Applicants respectfully traverse this rejection.

The Examiner, acknowledges that “[n]ucleic acids consisting of SEQ ID NO: 7212 meet the written description requirements.” Final Action at page 7. However, the Examiner argues that “the basis for the instant rejection is the lack of written description for molecules comprising subsequences of SEQ ID NO: 7212 and complements thereof, as well as molecules comprising nucleic acids less than 100% identical to SEQ ID NO: 7212.” *Id.* Applicants respectfully disagree.

The purpose of the written description requirement is to ensure that the inventor had possession of the claimed subject matter, *i.e.*, to ensure that the inventor actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479,

45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventor had possession of the claimed invention, even if not every nuance, then the written description has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. A person of ordinary skill in the art would, after reading the present specification, understand that Applicants had possession of subsequences of nucleic acid molecules SEQ ID NO: 7212, complements, and sequences with the recited percent identity and therefore, the claimed invention.

For example, the present application describes more than just the nucleotide sequence recited by the claims (SEQ ID NO: 7212). For example, the specification describes fragment nucleic acid molecules (*see, e.g.*, specification at page 20, line 22 through page 21, line 2) as well as combigene positions within the sequence, as well as the start and ending positions for each of the proteins encoded within the claimed sequences (*see, e.g.*, specification at page 104, line 4 through page 110, line 35, and Table 1).

Furthermore, the specification discloses gene sequences, corresponding sequences from other species, mutated sequences, SNPs, polymorphic sequences, promoter sequences, exogenous sequences, and so forth (*see, e.g.*, specification at page 25, line 14 through page 27, line 24; page 30, line 24 through page 42, line 6; and page 60, line 26 through page 68, line 2, Table 1 and the sequence listing). The specification also describes appropriate hybridization conditions (*see, e.g.*, specification at 22, line 25 through page 23, line 11); nucleic acid molecules comprising nucleic acid sequences

having conservative variations or encoding amino acid sequences having conservative substitutions (*see, e.g.*, specification at page 38, line 5 through page 42, line 6); fusion protein or peptide molecules or fragments thereof encoded by the nucleic acid molecules of the present invention (*see, e.g.*, specification at page 43, lines 8-19); nucleic acids comprising introns, intron/exon junctions, or both (*see, e.g.*, specification at page 42, lines 9-15); plant homologue proteins (*see, e.g.*, specification at page 43, line 20 through page 44, line 11); site directed mutagenesis of the claimed nucleic acid molecules (*see, e.g.*, specification at page 71, line 19 through page 73, line 6); and vectors comprising the claimed nucleic acid molecules and methods of transforming plants (*see, e.g.*, specification 73, line 7 through page 92, line 9). Furthermore, the addition of other nucleotides or detectable labels to the disclosed nucleotide sequences (*e.g.*, SEQ ID NO: 7212) is readily envisioned by one of ordinary skill in the art upon reading the present specification, as described for example at page 21, lines 20-24 (describing sequences with labels to facilitate detection); as also described for example at page 43, lines 13-19 (describing fusion peptide molecules encoded by the claimed nucleic acid molecules); at page 23, line 12 through page 24, line 97 (describing sequences having particular sequence identity to the claimed nucleic acid molecules); and at page 71, line 19 through page 73, line 6 (describing site-directed mutagenesis).

The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids can be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). Applicants have satisfied that test for written description.

In particular, Applicants have disclosed common structural features, for example the nucleotide sequence of SEQ ID NO: 7212. For example, if a particular nucleic acid molecule contains the nucleotide sequence of SEQ ID NO: 7212, then it is a member of the claimed genus of nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 7212.¹ Moreover, closely related nucleic acid molecules falling within the scope of the claimed invention are readily identifiable - they either contain the nucleic acid sequence of SEQ ID NO: 7212 or share a claimed identity with SEQ ID NO: 7212, or they do not. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the specification. Thus, contrary to the Examiner's analysis, claims 1 and 8-12 are supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112, and the rejection should be reversed.

In light of the detailed disclosure of the present application, one skilled in the art, after reading the present specification, would clearly know if a nucleic acid molecule contains one of the recited nucleotide sequences. Thus, claims 1 and 8-12 are supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112, and the rejection should be reversed. Reconsideration and withdrawal are respectfully requested.

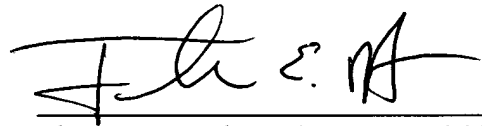
¹ The same argument applies with equal force to every genus of the claimed nucleic acid molecules. For example, if a nucleic acid molecule contains a nucleic acid sequence that has 95% identity with SEQ ID NO: 7212, then it is a member of the claimed genus of nucleic acid molecules having between 95% and 100% identity with SEQ ID NO: 7212. *See* claim 9.

Conclusion

In view of the foregoing remarks, Applicants respectfully submit that the present application is now in condition for allowance, and notice of such is respectfully requested. The Examiner is encouraged to contact the undersigned should any additional information be necessary for allowance.

Respectfully submitted,

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